## In the matter of International Patent Application WO 00/31545, Kings College, London

## **DECLARATION**

- I, Kenneth J Smith, do hereby declare and state :-
  - 1. I am Professor of Neurobiology and Head of the Neuroinflammation Research Group in the Department of Neuroimmunology, Guy's, King's, and St. Thomas' School of Medicine, Guy's Campus, Kings College London.
  - 2. I have been asked to advise on the meaning of a term used in International Patent Application WO 00/31545 as published on 2<sup>nd</sup> June 2000. I have not considered any other aspect of this application.
  - 3. The term in question is "myelin neurofilaments". This term has no recognised usage in the field of Neuroscience. Myelin is the insulating layer that surrounds the axons of many neurons in the central and peripheral nervous system. Neurofilaments are structures present in neurons. Myelin and neurofilaments are separate and distinct from one another. Antibodies to myelin proteins and antibodies to neurofilaments are found in certain disease situations but these are separate and distinct antibodies.
  - 4. I have considered the possibility that the term "myelin neurofilaments" is being used in this application to denote some particular type of neurofilaments, in which case I would have expected to find some explanation of its intended meaning. No such explanation is to be found in the description or the claims of the application. I therefore believe that no special use of the term is being made.
  - 5. I have considered the possibility that the term "myelin neurofilaments" has been used by the patent draftsman by mistake, in place of the sole term "neurofilaments" having the established meaning given in paragraph 3 above. I understand that the Applicant has affirmed this to be so.



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6. In my opinion, after reading the text of the application as a whole, I believe that the term has obviously been used by mistake, in place of the correct term "neurofilaments", and that persons skilled in the field of Neuroimmunology would reach the same conclusion as I have. This conclusion is supported by the fact that, in the Experimental section of the application, reference has been made to commercially available neurofilaments from bovine spinal cord as one of the test antigens used in the method and kit claimed in the application. These are stated in the manufacturer Sigma's catalogue to be "intermediate filaments found in axons of large myelinated fibers, most axons, astrocytes and Schwann cells". I understand that the Applicant has previously drawn attention to this fact.

DECLARED by me

KENNETH J SMITH

Date 4 Occember 2003